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S14-23

January 31, 2005

Mr. Gary M. Jackson,
Assistant Administrator for Size Standards
409 Third Street, SW
Washington, DC 20416

Re: RIN 3245-ZA02

Dear Administrator Jackson:

This is a formal response to Advance Notice of Proposed Rulemaking of 13 CFR Part 121 issued September 15, 2004. My name is Leo Liu, and I am the founder and president of Cambria Biosciences, a start-up biotechnology company in the Boston area. My comments pertain only to the section, "Participation of businesses majority-owned by Venture Capital Companies in the SBIR Program." I believe that small business concerns that are more than 51% owned by for-profit institutional venture capital companies should be excluded from eligibility for the SBIR program for the following reasons:

- The primary objective of the SBIR program is to provide early-stage funding to innovative small companies for high-risk, early discovery-stage research projects that are not yet commercially feasible. Venture capital financing, in contrast, is primarily for commercializing technology for which feasibility has already been demonstrated. Venture capital funds are largely drawn from institutional limited partners with billions of dollars to invest, including university endowments, pension funds, and high net-worth individuals and family trusts. The primary beneficiaries of the SBIR program are intended to be the applicant small business firm and the awarding federal agency, not institutional investors. To allow venture capital-controlled companies to receive phase I and phase II SBIR awards will subvert the original legislative intent and spirit of the SBIR program.

- Drug discovery and development require tremendous amounts of capital and time. It is impossible for a company to fund biopharmaceutical R&D from the earliest stages by selling equity alone. Start-up companies need to conserve equity early on by generating revenues and obtaining non-dilutive sources of funding such as research grants. This critical function is superbly well served by the SBIR program through its Phase I and Phase II Awards. In contrast, progressive venture capital involvement in company financing and control is appropriate for later Phase III commercialization, when larger amounts of capital provided by private and public equity markets are needed to fund the later and more expensive stages of clinical testing required for FDA approval of a new drug.

- Companies operating in "small markets" will suffer disproportionately if VC-controlled companies are allowed to compete for SBIR funding. Biotechnology companies that focus on unmet needs for less common or "orphan" diseases, such as cystic fibrosis and ALS, are unlikely to generate interest from venture capital firms, and must rely on alternative sources of R&D funding such as SBIR grants and disease foundations. Furthermore, by "small markets," I also refer to small businesses in geographic locales that are isolated from major financial centers, such as Maine or Montana, where it is more diificult to attract venture capital funding.

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I will close with a cautionary example. Because the current SBA standard has apparently not been strictly enforced in the past, many venture capital-controlled biotechnology companies have applied for and received SBIR funding. One such company is Targacept, a biopharmaceutical company in Winston-Salem, NC, that is developing drugs based on a class of proteins known as nicotinic acetylcholine receptors. From 1997-2000, Targacept was incubated as a subsidiary within a large company with a vested interest in the biological actions of nicotine, namely R.J. Reynolds Tobacco, a Fortune 100 multinational corporation. Targacept was spun out in 2000 with $30.4 million of venture capital financing, followed by a second venture round of $59.5 million in 2003. Targacept received SBIR funding in 2003-2004, and the company's Community Affairs & Grants Specialist has advocated that VC- backed small businesses be eligible to compete for SBIR funding (www.zyn.com/sbir/articles/vc/). According to S-1 documents filed on May 14, 2004 for an Initial Public Offering, 72.3% of the company's outstanding stock is owned by seven principal stockholders comprised of venture capital funds as well as the parent company, R.J. Reynolds Tobacco Holdings, Inc. In this instance, I believe the goals of the original legislation to promote innovation by small businesses have been subverted to the benefit of institutional investors and large corporations.

In light of these considerations, I urge you to protect and promote the original spirit and letter of 13 CFR 121.103 in order to ensure this important source of American technological innovation. Thank you for your attention, and I would be pleased to answer any questions that you might have on this issue.

Yours sincerely,

Leo Liu

Leo X. Liu, MD
President and Chief Scientific Officer
Cambria Biosciences LLC